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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,325	09/12/2005	Kevin Woehr	54104/THD/K163	5105

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EXAMINER	
ANDERSON, MICHAEL J	
ART UNIT	**PAPER NUMBER**
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No.	Applicant(s)	
	10/520,325	WOEHR, KEVIN	
	Examiner	Art Unit	
	Michael J. Anderson	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/23/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The references cited 8/23/2007 have been considered, and will be listed on any patent resulting from this application since they were provided on a separate list in the Information Disclosure Statement (IDS) Form PTO/SB/08 in compliance with 37 CFR 1.98(a)(1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woehr et al (USPN 6,117,108) in view of Rogers et al. (USPN 5,405,323). Woehr ('108) discloses a safety intravenous (IV) catheter insertion device.

In regards to claims 1, 4, 7, and 9 Woehr ('108) discloses a catheter insertion device (10) comprising a hollow-cylindrical catheter hub (26), catheter tube (24), needle hub(12), a hollow needle (16), a needle guard element (40) on the needle within the catheter hub (36) and an engaging section for the needle guard element which engages with an engaging means formed near the needle tip when the hollow needle is removed from the catheter (col. 5, lines 22-46), a radial projection (68) projecting radially from the inner circumference of the catheter hub (26), which is configured to engage with the needle guard element in the ready position (figure 4A) and an inner circumference with a radial projection (62) for positioning the needle guard element. A needle guard element (120) formed as a spring clip (figures 10A, 10B, 11A and 11B) which has diametrically opposite spring arms (122 and 124) starting from a rear wall provided with a bore (134), wherein bent end sections of the spring arms overlap and block the needle tip when the engaging means (138) of the needle comes to abut on the rear wall (figure 10B). However, Woehr lacks a check valve disposed between the catheter tube and the needle guard element in the catheter hub through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle. Rogers ('323) discloses a check valve (10) disposed between the catheter tube (16) and the needle guard element (26 and 33) in the catheter hub (13) through which the hollow needle extends in the ready position and which automatically closes after the removal of the needle (figures 1 and 2 and Col. 3, lines 30-55 and Col. 4, lines 23-62). Since the function of catheters is to allow controlled delivery of medicaments or removal of blood from a patient's vessel, it would have been obvious to one of ordinary skill in the art to

modify Woehr's catheter insertion device with a check valve to control intravenous fluid transmission and fluid sampling by closing the fluid pathway after removing the needle.

Woehr ('278) discloses all the limitations of claim1 in addition to a catheter hub (26) having a distal hub element (28) and a proximal hub element (30). However, concerning claim 2, Woehr lacks a check valve held between a distal hub element and a proximal hub element which are joined to one another. Rogers ('323) discloses a check valve (10) held between a distal hub element (55) and a proximal hub element (53) which are joined to one another (figure 2). The purpose of the check valve is to control fluid transmission in or out of the body vessel after the catheter has been placed. It would have been obvious to one of ordinary skill in the art to modify Woehr's catheter insertion device with a check valve positioned between a distal hub element and a proximal hub element of a catheter hub to control fluid transmission from a catheter.

Woehr ('108) discloses the limitations of claim 1. However, concerning claim 3, Woehr lacks a check valve with a plurality of radially elastically expandable valve flaps configured to be moved into an open position by fluid pressure generated from a syringe. Rogers ('323) discloses a check valve (10) with two valve flaps (figure 2 and 9) configured to be moved to an open position by fluid pressure from a syringe (col. 4, lines 45-55). It is known in the art that check valves can have multiple flaps to control fluid transmission such that it would have been obvious to one of ordinary skill in the art to modify Woehr's catheter insertion device with a check valve configured to be moved to an open position by fluid pressure control fluid transmission.

Woehr ('108) teaches the limitations of claim 1. However, concerning claims 5 and 6, Woehr lacks a check valve with valve disc, which has radial slits starting from a middle section of the valve disc and a valve actuating element, which is displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element, and an actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section. Rogers ('323) discloses a check valve comprised of a valve disc (51), radial slit (48), and a valve actuating element (12) displaceably guided in the catheter hub and has a hollow space for receiving the needle guard element (34), and an actuating element formed as a hollow cylinder with a truncated cone-shaped distal end section Figure 2 and Col. 4, lines 23-62). Check valves are well known in the art have been comprised of valve discs, radial slits and an actuating element such that it would be obvious to one of ordinary skill in the art to modify Woehr with Rogers to include a check valve that controls intravenous fluid delivery.

Woehr ('108) teaches the limitations of claims 1, and 5. However, concerning claim 8, Woehr lacks a valve actuating element having a truncated cone-shaped abutting section. Rogers ('323) discloses a valve actuating element having a truncated cone-shaped abutting section (12) (figure 2).

In regards to claims 10 and 11, Woehr ('108) teaches a catheter tube (24) attached to an end of a catheter hub (26), the catheter tube comprising a lumen and the catheter hub comprising an interior cavity (figure 1A); a needle (16) defining a needle axis attached to an end of a needle hub (12), projecting through the lumen of the catheter tube and comprising an engaging section near a needle tip (60 and figures 1A

–1D). A needle guard element (120) comprising two needle guard arms (122 and 124) crossing the needle axis of the needle positioned inside the catheter hub (figure 10A) and an opening (134) adapted to contact the engaging section of the needle (figure 10B). Woehr lacks a check valve positioned adjacent to the catheter hub and between the catheter hub and the needle hub. Rogers ('323) discloses a check valve (10) positioned adjacent to the catheter hub (11) and between the catheter hub and the needle hub (18). IV catheters have been well known in the art as a means to control fluid transmission into a patient and out of a patient, it would have been obvious to one of ordinary skill in the art to modify Woehr's ('108) safety IV catheter Rogers' ('323) catheter check valve assembly by positioning the check valve between the catheter hub and the needle hub in order to control fluid transmission after a catheter had been placed in a patient's vessel and the needle removed.

With regards to new claims 12-20, both Woehr's ('108 and '278) disclose (figures 10-11) the added structure describing the needle guard system. Woehr lacks a check valve positioned adjacent to the catheter hub and between the catheter hub and the needle hub. Rogers ('323) discloses a check valve (10) positioned adjacent to the catheter hub (11) and between the catheter hub and the needle hub (18). IV catheters have been well known in the art as a means to control fluid transmission into a patient and out of a patient, it would have been obvious to one of ordinary skill in the art to modify Woehr's ('108) safety IV catheter Rogers' ('323) catheter check valve assembly by positioning the check valve between the catheter hub and the needle hub in order to

control fluid transmission after a catheter had been placed in a patient's vessel and the needle removed.

Response to Amendment

The present communication responds to the Amendment of 08/23/2007. By this communication, claim 1 was amended and new claims 12-20 were added. No new matter was added. Claims 1-20 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments filed 8/23/2007 have been fully considered but they are not persuasive. Woehr ('108 and '278) disclose all of the claim limitations of the present invention except for the "check valve" system that prevents syringe fluid from leaking after use. Rogers ('323) discloses the fluid leak prevention check valve assembly and other variations (column 1, lines 49-51). The structure of Rogers check valve assembly is not the same as the "check valve" system of Woehr ('108 and '278). However, the concept of using a check valve disc (7) in the instant application, is disclosed by Rogers ('323) as a duckbill valve. Furthermore, applicants 8/23/2007 IDS contains Wolbring (USPN 5,456,675) in which the instant check valve structure is disclosed (48).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson
Examiner
Art Unit 3767

MJA
11/7/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER